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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,768	05/27/2005	Naoki Taoka	Q88078	2449
23373 7590 01/07/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
SAUCIER, SANDRA E				
ART UNIT		PAPER NUMBER		
1651				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,768

Applicant(s)

TAOKA ET AL.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12, 17-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12, 17-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 7-12, 17-19, 21-26 are pending and are considered on the merits.

Specification

The disclosure is objected to because of the following informalities: On page 24, line 15, there is an incomplete sentence. Please amend without the addition of new matter. Appropriate correction is required.

Claim Rejections – 35 USC § 112

Claims 7-12, 17-19, 21-26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims do not have a recovery step for the compounds produced.

The claims are incomplete in the absence of a recovery step for the products produced. While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Response to Arguments

Applicant's arguments filed 10/8/08 have been fully considered but they are not persuasive. Applicant argues that what is known and conventional need not be claimed. This argument is not persuasive because the claim omits an essential element. While this step is conventional, an active step in the process has been omitted, which makes the claim incomplete.

Claim Rejections – 35 USC § 102/103

Claims 7, 8, 11 remain rejected under 35 U.S.C. 102(b) as being clearly

anticipated by, or in the alternative, under 35 U.S.C. 103(a) obvious over US 4,734,367 [A] in light of Barth *et al.* [U].

The claims are directed to a method for making optically active 3-hydroxy-2-substituted-propionic acid esters comprising: subjecting 2-formylacetic acid ester of formula 2 to a reduction catalyzed by an enzymatic source from various genera.

US 4,734,367 demonstrates a stereoselective fermentative reduction of 2-formylacetic acid ester to (R) or (S) 3-hydroxy-2-substituted propionic acid. Microbes used are preferably aerobic or facultative aerobic yeasts, fungi or bacteria (col. 1, l. 68) and claim 1, preferred microbes belong to the genus *Candida* and other preferred genera, table column 2.

Barth *et al.* disclose that a microbe belonging to the genus *Yarrowia* has been also classified as belonging to the genus *Candida* by those of skill in the art (abstract), see particularly *Yarrowia lipolytica*.

Some microbes belonging to the genus *Candida* have been reclassified as *Yarrowia*. Therefore, because of the cross classification of these microbes by those of skill in the art, use of the microbes from the genus *Yarrowia* to effect the instant biotransformation is considered to be the same as or so closely related as to be obvious over transformation by microbes from the genus *Candida* which is clearly a preferred genus in the cited prior art to produce preponderantly either the (R) or the (S) isomer by reduction of the compound of formula 2.

Claims 17-19, 24, 25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,734,367 [A] as applied to claims 7, 8, 11 above, and further in view of Kido *et al.* [W].

The claims are further directed to the formation of the compound of

formula (2) by reacting an acetic acid ester (1) with a base and formic ester and extracting impurities with an organic solvent and transferring (2) into a water layer prior to the microbial reduction.

Kido *et al.* disclose the reaction of an acetic ester derivative (1) with a base and a formic ester to form (2), adding organic solvent and water to the reaction mixture and removing the aqueous layer containing (2), page 5471.

The formation of the substrate (2) of the microbial reduction reaction by reacting an acetic acid ester with a base and formic ester, adding water and organic solvent and removing the organic layer prior to the use of the substrate (2) in microbial reduction methods as disclosed in US 4,734,367, would have been obvious because Kido *et al.* disclose such a reaction to form substrate (2) and US 4,734,367 also teaches that the substrates can be obtained by organic synthesis (col. 5, l. 17).

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions of microbes recited in the claims in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 10/8/08 have been fully considered but they are not persuasive.

Applicant argues that not all of *Candida* is now also classified as *Yarrowia* and not all of *Candida* can catalyze the stereo-selective reduction of the present invention and none of the *Candida* species disclosed in US '367 has ever been reclassified as *Yarrowia*. While it may be true that none of the species of *Candida* in US '367 have been reclassified as belonging to *Yarrowia* genus, the claim broadly claims the use of any and all *Yarrowia*, which group

overlaps with microbes in the genus *Candida*, and in particular, *Candida lipolytica* is the same organism as *Yarrowia lipolytica*, see Barth *et al.* [U] The reference states without reservation that yeasts of the genus *Candida* may be used to enantioselectively reduce the instant starting compound, which includes the species *Candida lipolytica* which is also known as *Yarrowia lipolytica*. Thus, the claim is not free of the prior art, especially with regard to the use of *Yarrowia*. Although none of the *Candida* species specifically mentioned in US '367 is *lipolytica*, the generic disclosure and claim 1 encompass the use of all microbes of the genus *Candida*, including *Candida lipolytica*.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651